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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/718,188

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EXAMINER

BLATT, ERIC D

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/718,188	<b>Applicant(s)</b> YANUMA ET AL.	
	<b>Examiner</b> Eric Blatt	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 45-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-15, 17-19, 21, 22 and 45-47 is/are rejected.
- 7) ☒ Claim(s) 12, 16, and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-7 and 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 3-7, claim 3 recites, "the X-ray chip is disposed in a projected state outside a diametric direction with respect to an axis of the second cylindrical member in a state in which the stent is disposed in the cylindrical member." There are a number of ambiguities in this language. It is unclear what it means for a chip to be disposed in a projected state, or for a chip to be disposed outside a direction. The claim also seems to recite that the chip is disposed in a first geometrically defined state, and also in a state in which the stent is disposed in the cylindrical member. It is unclear whether the x-ray chip is disposed in both states. Further, Examiner does understand what it means for the chip's state to be defined by the position of the stent. Claim 3 recites "the cylindrical member" wherein more than one cylindrical member has been previously recited. Finally, from the context of this recitation of the cylindrical member, it appears that the claim is suggesting that the stent is disposed in the second cylindrical member, but claim 1, from which claim 3 depends, recites that the stent is disposed inside the first cylindrical member and over the second cylindrical member. The

Art Unit: 3734

language of claim 3 is sufficiently unclear so as to prevent present examination of the subject matter of said claim.

Regarding claims 45-47, said claims recite that the second cylindrical is inserted inside the first cylindrical member and that the stent is charged in the second cylindrical member by the first cylindrical member. How would an outer cylinder affect a stent inside an inner cylinder? It seems from the disclosure that the claim should recite that the stent is charged over the second cylindrical member by the first cylindrical member. Said claims also recite, "pulling the first cylindrical member out of the second cylindrical member." The claims had established that the second cylindrical member is inside, not outside, the first cylindrical member. The claims also recite "using the holding mechanism to hold the second cylindrical member with respect to the forceps channel of the endoscope," and "pulling the first and second cylindrical members out of the forceps channel of the endoscope while releasing a state of the first cylindrical member held by friction." These recitations seem to contradict one another. Is the first or second cylindrical member held with respect to the forceps channel? Lastly, claim 47 recites "holding a target portion between the holding mechanism . . . and the second cylindrical member to regulate the movement of the second cylindrical member." The target portion seems to be a portion of a patient's anatomy. It is unclear how the target portion could be held between the holding mechanism and the second cylindrical member. Further, it is unclear how doing so might regulate the movement of the second cylindrical member.

Art Unit: 3734

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 45-47 recite "introducing a first cylindrical member and a second cylindrical member inserted inside the first cylindrical member to a target portion," and "pulling the first cylindrical member out of the second cylindrical member." Applicant's disclosure does not sufficiently enable one skilled in the art to perform such a method wherein an outer member is pulled out of an inner member disposed within the outer member.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, and 8-11, 13-15, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Randall et al. (US 6,514,261).

Randall discloses a stent delivery system (Figures 1 and 17-20) comprising a first cylindrical member 10 capable of being inserted into a forceps channel of an endoscope, a second cylindrical member 12, 14 inserted within first cylindrical member 10 and capable of advancing/retracting with respect to the first cylindrical member 10, and a stent 16 disposed between the first and second cylindrical members. The second cylindrical member includes a holding mechanism 98, 100 that is capable of holding a relative position of the second cylindrical member with respect to an endoscope. The second cylindrical member 12, 14 includes an x-ray chip 26 recognized at the time of irradiation with an x-ray and disposed in a position where the stent is charged. (Column 4, Lines 12-13)

The holding mechanism 98, 100 is fixed relative to the wire guide port shown at the top of Figures 17, 19, and 20. Second cylindrical member 12 is also fixed relative to said wire guide port. (Column 4, Lines 63-64) Thus, cylindrical member 12 is fixed relative to the holding mechanism 98, 100. Holding mechanism 98, 100 comprises a third cylindrical member 100 that is directly slidable on the first cylindrical member 10 outside the first cylindrical member. The third cylindrical member is capable of being inserted into a working channel of an endoscope wherein the working channel has an inner diameter that closely matches the outer diameter of the third cylindrical member 100 such that the third cylindrical member 100 frictionally engages the working channel of the endoscope. Thus, holding mechanism 98, 100 is capable of holding a relative

Art Unit: 3734

position of the second cylindrical member with respect to the forceps channel of the endoscope.

Regarding claims 9, 10, 13, 14, 17, and 18, the wire guide port is interpreted as a connection member that connects the third cylindrical member 100 to the second cylindrical member 12. Portion 98 of holding mechanism 98, 100 is considered to be a holder 98. Holder 98 is capable of being attached to and disposed on an endoscope.

Regarding 11, 15, and 19, the wire guide port is considered to be a fixing tool which connects the holder to the second cylindrical member. The wire guide port may be disassembled such that at least second cylindrical member 12 may be removed. Thus, the wire guide port connects the holder to the second cylindrical member in a detachably fixed state.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randall et al. (US 6,514,261).

Randall discloses all elements of claims 21 and 22 as previously discussed except for a hydrophilic lubrication being disposed on the tip end of the first cylindrical member and the tip-end chip 26 of the second cylindrical member. It was notoriously

Art Unit: 3734

old and well known to provide hydrophilic lubricious coatings on distal portions of minimally invasive devices. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Randall by providing a hydrophilic lubricant on the tip end of the first cylindrical member and the tip-end chip 26 of the second cylindrical member in order to minimize tissue damage as said elements are advanced through a patient's body.

### ***Allowable Subject Matter***

Claims 12, 16, and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Said claims recite structural elements of a fixing tool that are not fairly taught by the prior art.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-22 and 45-47 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.



Art Unit: 3734

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/  
Primary Examiner, Art Unit 3734

Eric Blatt  
571-272-9735